Claims:

1. A novel soft gelatin capsule comprising a fill material consisting essentially of S-adenosylmethionine (SAMe) salt disposed within an enteric coated soft gelatin film.

2. A capsule as claimed in claim 1 wherein the fill material comprises a core of SAMe salt coated with lipophilic material, which is further provided an oily matrix, antioxidants and preservatives.

3. A capsule as claimed in claim 1 wherein the salts of SAMe are monosulphate tosylate or disulphate tosylate salts.

4. A capsule as claimed in claim 1, wherein SAMe is present in an amount ranging from 425 mg to 440 mg depending on assay, potency, moisture content and overage.

5. A capsule as claimed in claim 2 wherein the lipophilic material coated over the S-adenosylmethionine salt is selected from stearic acid, carnuaba wax, beeswax, polyoxyethylene sorbitan monooleate, cetyl alcohol, glyceryl monostearate, cetostearyl alcohol and glyceryl behanate.

6. A capsule as claimed in claim 2 wherein the lipophilic material is diluted with dichloromethane or isopropylalcohol.

7. A capsule as claimed in claim 2 wherein the amount of lipophilic material is 15 to 20%, preferably 16%.

8. A capsule as claimed in claim 2 wherein the ratio of lipophilic material to S-adenosylmethionine salt is 5:1.

9. A capsule as claimed in claim 2 wherein the oil in the oily matrix is composed of an oil selected from soya oil, arachis oil, wheat germ oil, corn oil and rice bran oil.

10. A capsule as claimed in claim 2 wherein the amount of oil is 50 to 55% w/w, preferably 53% of the total fill material.

11. A capsule as claimed in claim 2 wherein the antioxidants are selected from butylated hydroxy toulene NDGA and butylated hydroxy anisole.

12. A capsule as claimed in claim 2 wherein the amount of antioxidants is 0.1%w/w.

13. A capsule as claimed in claim 2 wherein the preservatives are selected from methyl and propyl parabens.

14. A capsule as claimed in claim 1 wherein the soft gelatin film further comprises softening agents, plasticizers, opacifying agents, preservatives and colouring agents.

15. A capsule as claimed in claim 14, wherein the gelatin present in the film is from 40 to 60% w/w.

16. A capsule as claimed in claim 14 wherein the softening agent is selected from glycerol, glycerine, triacetin, sorbitol, sorbitan anhydrides and mannitol.

17. A capsule as claimed in claim 14 wherein the amount of softening agent is 10% to 15%.

18. A capsule as claimed in claim 14 wherein the plasteizer is selected is polyethylene glycol 200 (PEG 200).

19. A capsule as claimed in claim 14 wherein the amount of plasticizer is about 25 to 30%.

20. A capsule as claimed in claim 14 wherein the opacifiers is selected from titanium dioxide and/or iron oxides.

21. A capsule as claimed in claim 14 wherein the opacifier is present in an mount of 0.2 to 0.5%w/w.

22. A capsule as claimed in claim 14 wherein the colouring agent is iron oxide yellow.

23. A capsule as claimed in claim 14 wherein the amount of colouring agent present is 0.25%w/w.

24. A capsule as claimed in claim 14 wherein the preservative is methyl or propyl parabens.

25. A capsule as claimed in claim 14 wherein the amount of preservatives is 0.2 to 0.5% w/w.

26. A capsule as claimed in claim 1 wherein enteric coating on the capsule is selected from a coating of hydroxypropylmethyl cellulose phthalate (HPMCP), hydroxypropylmethyl cellulose succinate (HPMCS), carboxymethyl cellulose (CMEC) and methylacrylic acid copolymer.

27. A capsule as claimed in claim 1 wherein the thickness of the soft gelatin film is about 0.9 to 1.1 mm.

28. A capsule as claimed in claim 1, wherein the enteric coating sustains a pH of 5.5 to 6.8.

29. A capsule as claimed in claim 1, wherein the thickness of the enteric coating ranges from 250 to 350μ.

30. A capsule as claimed in claim 1, wherein the enteric coating essentially releases the fill material within 2 hours of oral administration.

31. A capsule as claimed in claim 1, wherein the device is a single piece capsule sealed at the seamline.

32. A capsule as claimed in claim 1, wherein said opacifying agent comprises titanium dioxide or iron oxide present in an amount of 0.2 to 0.5%w/w.

33. A capsule as claimed in claim 1, wherein the preservative comprises methyl- or propyl-parabens present in an amount of 0.1 to 0.5% w/w.

34. A capsule as claimed in claim 1, wherein said fill material comprises SAMe, lipophilic agent, oily base, anti-oxidants and preservatives.

35. A method of preparing a soft gelatin capsule comprising SAMe, said method comprising the steps of:

a. coating SAMe salt with a lipophilic material to obtain granules,

b. coating the granules obtained in step (a) with an oily matrix, antioxidants and preservatives to form a lipid suspension,

c. disposing the lipid suspension within a soft gelatin film, and

d. providing the soft gelatin film with an enteric coating to obtain an enteric coated soft gelatin capsule.

36. A method as claimed in claim 35 wherein the salts of SAMe are monosulphate tosylate or disulphate tosylate salts.

37. A method as claimed in claim 35, wherein SAMe is present in an amount ranging from 425 mg to 440 mg depending on assay, potency, moisture content and overage.

38. A method as claimed in claim 35 wherein the lipophilic material coated over the S-adenosylmethionine salt is selected from stearic acid, carnuaba wax, beeswax, polyoxyethylene sorbitan monooleate, cetyl alcohol, glyceryl monostearate, cetostearyl alcohol and glyceryl behanate.

39. A method as claimed in claim 35 wherein the lipophilic material is diluted with dichloromethane or isopropylalcohol.

40. A method as claimed in claim 35 wherein the amount of lipophilic material is 15 to 20%, preferably 16%.

41. A method as claimed in claim 35 wherein the ratio of lipophilic material to S-adenosylmethionine salt is 5:1.

42. A method as claimed in claim 35 wherein the oil in the oily matrix is composed of an oil selected from soya oil, arachis oil, wheat germ oil, corn oil and rice bran oil.

43. A method as claimed in claim 35 wherein the amount of oil is 50 to 55% w/w, preferably 53% of the total fill material.

44. A method as claimed in claim 35 wherein the antioxidants are selected from butylated hydroxy toulene NDGA and butylated hydroxy anisole.

45. A method as claimed in claim 35 wherein the amount of antioxidants is 0.1%w/w.

46. A method as claimed in claim 35 wherein the preservatives are selected from methyl and propyl parabens.

47. A method as claimed in claim 35 wherein the soft gelatin film further comprises softening agents, plasticizers, opacifying agents, preservatives and colouring agents.

48. A method as claimed in claim 35, wherein the gelatin present in the film is from 40 to 60% w/w.

49. A method as claimed in claim 35 wherein the softening agent is selected from glycerol, glycerine, triacetin, sorbitol, sorbitan anhydrides and mannitol.

50. A method as claimed in claim 35 wherein the amount of softening agent is 10% to 15%.

51. A method as claimed in claim 35 wherein the plastcizer is selected is polyethylene glycol 200 (PEG 200).

52. A method as claimed in claim 35 wherein the amount of plasticizer is about 25 to 30%.

53. A method as claimed in claim 35 wherein the opacifiers is selected from titanium dioxide and/or iron oxides.

54. A method as claimed in claim 35 wherein the opacifier is present in an mount of 0.2 to 0.5%w/w.

55. A method as claimed in claim 35 wherein the colouring agent is iron oxide yellow.

56. A method as claimed in claim 35 wherein the amount of colouring agent present is 0.25%w/w.

57. A method as claimed in claim 35 wherein the preservative is methyl or propyl parabens.

58. A method as claimed in claim 35 wherein the amount of preservatives is 0.2 to 0.5% w/w.

59. A method as claimed in claim 35 wherein enteric coating on the method is selected from a coating of hydroxypropylmethyl cellulose phthalate (HPMCP), hydroxypropylmethyl cellulose succinate (HPMCS), carboxymethyl cellulose (CMEC) and methylacrylic acid copolymer.

60. A method as claimed in claim 35 wherein the thickness of the soft gelatin film is about 0.9 to 1.1 mm.

61. A method as claimed in claim 35, wherein the enteric coating sustains a pH of 5.5 to 6.8.

62. A method as claimed in claim 35, wherein the thickness of the enteric coating ranges from 250 to 350μ.

63. A method as claimed in claim 35, wherein the enteric coating essentially releases the fill material within 2 hours of oral administration.

64. A method as claimed in claim 35, wherein the device is a single piece capsule sealed at the seamline.

65. A method as claimed in claim 35, wherein said opacifying agent comprises titanium dioxide or iron oxide present in an amount of 0.2 to 0.5%w/w.

66. A method as claimed in claim 35, wherein the preservative comprises methyl- or propyl-parabens present in an amount of 0.1 to 0.5% w/w.

67. A method as claimed in claim 35, wherein said fill material comprises SAMe, lipophilic agent, oily base, anti-oxidants and preservatives.